

Doc Code: AP.PRE.REQ

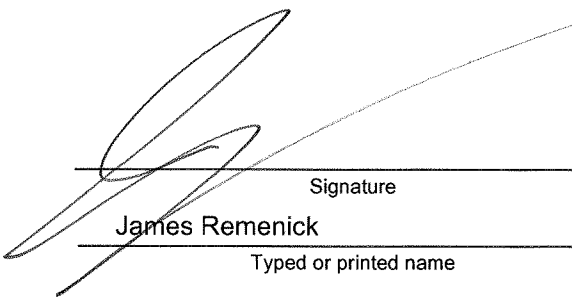
PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 8109.005.US	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____	Application Number  10/825,603	Filed  April 16, 2004	
	First Named Inventor  James Thacker		
	Art Unit  1644	Examiner  Kim, Yunsoo	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.      36,902</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.</p> <p>Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			



Signature  
James Remenick  
Typed or printed name  
202-659-0100  
Telephone number  
July 20, 2007  
Date

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: : Group Art Unit: 1644  
James D. Thacker :  
App. No.: 10/825,603 : Examiner: Yunsoo Kim  
Filed: April 16, 2004 :  
Title: PROPHYLACTIC AND THERAPEUTIC BENEFITS OF A NEW CLASS OF IMMUNE STIMULATING  
PEPTIDES

MAIL STOP – **AF**

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450; Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicant respectfully requests the United States Patent and Trademark Office (“PTO”) to review the rejections set forth in the final Office Action, mail dated April 20, 2007.

**I. Brief Prosecution History**

Applicant received a non-final Office Action, mail dated October 25, 2006, wherein Applicant’s claims 1-14, 17, 20, and 25-27 were rejected, under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled and described by the specification. Applicant, though traversing the rejection, solely to expedite prosecution, incorporated into claim 1 a plurality of fatty acids as previously recited in claim 4 and a functional limitation of increasing patients’ effective innate immune system response, thus adding both physical and chemical properties as well as a correlated function, in satisfaction of the MPEP and the Revised Interim Guidelines for the Examination of Patent Applications (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001).

Applicant next received a final Office Action, mail dated April 20, 2007, which, although it withdrew all 35 U.S.C. § 102(b) rejections and asserted that Applicant’s claimed invention is free of art, essentially brought the same 35 U.S.C. § 112, first paragraph, rejections as in the previous non-final Office Action. The Examiner also rejected claims 1-19 and 25-41 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. At a May 17, 2007 interview with Examiner Yunsoo Kim and Supervisory Patent Examiner Christina Chan (the “Interview”), Supervisory Examiner Chan asserted that the scope of the claims, as it relates to enablement, was too broad because the claim recited the term “comprises” when referring to the sequence and, therefore, would read on a sequence of any length and any composition of amino acids. Applicant respectfully disagrees.

During the Interview the undersigned noted that the claims were not mere sequence claims, but contained additional scope-limiting recitations including a plurality of fatty acids and the function of increasing the effective innate immune system response. Supervisory Examiner Chan asserted that only the amino acid sequence was not enabled and suggested that limiting the sequence to “*consists of*” terminology would render the claims allowable.

The undersigned noted that SEQ ID NO 3 is what is commonly referred to in the art as a consensus sequence for the claimed peptide and that all claims required the limitation to this consensus sequence. The undersigned also noted that variations of this sequence are fully enabled in the specification (*see* Specification at pages 9-10 and Figure 5). For this reason alone, the specification is fully enabled for the phrase “comprising.” But in addition, the undersigned noted that pages 10-13 of the Specification describe how one skilled in the art would isolate peptides of the claimed invention, and the pages 20-26 of the Specification detail methods of production of Applicant’s claimed peptides. Therefore, the phrase “comprising” would be entirely proper and enabled, but, to expedite prosecution, Applicant would limit the instant claims to “consists essentially of” terminology.

Supervisory Examiner Chan asserted that this phrase (*i.e.* “consists essentially of”) may be acceptable, but requested that the undersigned show support for this exact phrase in the specification. The undersigned respectfully disagreed noting that the phrases “consists of” and “consists essentially of” are transitional phrases. The undersigned noted that support for transitional phrases was clear in the specification upon use of any non-limiting terminology, but also that support need not be “exact phrase” support. Proper support for transitional terminology as well as any terminology is support that is clear to those skilled in the art. Supervisor Chan agreed to consider Applicant’s position and, accordingly, Applicant filed a Response After Final (the “AF Response”) amending most claims to recite “consists essentially of” terminology and amending other claims to recite “consists of” terminology.

Applicant received an Advisory Action allowing only claims limited to “consists of” terminology, and rejecting claims that used “consists essential of” terminology. Accordingly, Applicant files this Pre-Appeal Request for Review with respect to claims containing the phrase “consists essentially of.”

## **II. The Instant Claims are Fully Enabled by the Specification.**

In the Advisory Action mail dated June 14, 2007, the Examiner once again alleges that the specification is not enabling and does not provide adequate written description for any isolated peptide comprising SEQ ID NOs 1, 2, 3 or 5. As Applicant has explained numerous times before, what is claimed is not any isolated peptide comprising any amino acid sequence.

The claimed peptide comprises a plurality of fatty acids and has a precise immunological function. In other words, Applicant is not claiming “any isolated peptide,” as alleged in the Advisory Action, but an isolated peptide with three limiting and distinct features, all fully enabled and described: (1) a specific and definite sequence; (2) a plurality of fatty acid; and (3) the function of increasing the effective innate immune system response. Thus, Applicant reasonably concludes that the pending claims are enabled by the specification and described in full compliance with the Revised Interim Guidelines which state that “partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function,” are all factors that are determinative of possession of the invention. Guidelines at 1106. As recited in claim 1, SEQ ID NO 3 provides at least a partial structure of the invention; the fatty acids provide further physical and chemical properties; and the immunological increase is a distinguishing and novel functional characteristic, but

an isolated peptide which possesses at least SEQ ID NO 3 (e.g. see claim 1) or SEQ ID No. 2 (see claim 8), or a peptide possessing SEQ ID No. 5 (see claim 12), or a peptide possessing a number of variations of these sequences (see claims 2, 3, 7, 9, 10, 11, 14, 17, 31, 34, 35, 36, and 39). SEQ ID No 1, which consists of 6 amino acids believed to be the consensus sequence of a small group of peptides, many of which are disclosed and their sequences provided in the specification. In this vein, Figure 5 shows not only the peptide limited to the consensus SEQ ID NO 3, but also variations that can exist in certain areas of the sequence.

Neither the final Office Action nor the Advisory Action takes into consideration any of the arguments made in Applicant's responses and summarized herein. Further, the Advisory Action simply reiterates an improper assertion that "the amended claims still read on isolated peptide of any length comprising SEQ ID NOs: 1-3 or 5 with plurality of fatty acids upto [sic] 3." This statement ignores the functional limitation of the claims as well as the scope limitation provided by the phrase "consists essentially of," as is set forth under MPEP 2111.03, which precludes features which would "materially affect" or change the "basic and novel" characteristics of the claimed invention. Because the basic and novel characteristics of the claimed invention are clearly disclosed in the claims and also in the specification, Applicant's claimed invention is fully enabled as was Applicant's claims when using the terminology "comprising" in reference to the peptide sequence.

The Advisory Action also alleges that "[t]he specification does not provide sufficient guidance as to which amino acid sequence can be added to the oligopeptides which retain a distinct functional property..." and that the Applicant has provided only a "limited working example." Advisory Action at 2. On the contrary, Applicant extensively teaches how one of ordinary skill in the art could modify the sequence by adding, for instance, 7, 8, 9 or more amino acids, all of which are described and enabled in the specification. The second full paragraph of page 9 also sets out the variations that have been experimentally discovered, such as the presence of arginine at the amino terminus and phenylalanine at the carboxy terminus. In the same paragraph, the variability of X1 and X2 in SEQ ID NO 2 is also described, lending further support and enablement for the word "comprises," and certainly at the very least for the phrase "consists essentially of," in the independent claims. In this vein, claim 13 includes all of the stated limitations, reached through the adding on of variations from throughout the specification, and this claim achieves one embodiment that the Examiner herself has stated that she believes to be enabled. See Advisory Action at 2, first multi-sentence paragraph.

For all of these reasons, Applicant respectfully asserts that, as of the filing date of the application, making a peptide with any of these sequence variations recited in the claims is well-known to those skilled in the art. Further, additional variations are enabled to those of ordinary skill in the art. No more is required under Section 112. Accordingly, the enablement rejection is moot and/or overcome.

### **III. The Examiner made a Number of Inaccurate Statements in the Advisory Action.**

The Examiner's allegations that the phrase "consists essentially of" is open-ended and that "even minor structural differences among structurally related compounds or compositions can result in substantially different or

deleterious biological activities” are erroneous and irrelevant, respectively. As Applicant explained at length in the AF Response and in this brief, “consists essentially of” is not open-ended, but simply serves to allow a certain amount of variation as described in the specification and recited in the dependent claims, all of which the Examiner herself has stated are enabled as evidenced from her assertion that these dependent claims would be immediately allowed if re-written in independent form. Interview. Moreover, “[t]he transitional phrase ‘consists essentially of’ limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.” MPEP 2111.03, quoting *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976) (emphasis in original). Therefore, the Examiner’s fear of including “deleterious biological activities” is unwarranted because precisely those kinds of material variations would be prohibited under the “consists essentially of” language. For at least this reason, the enablement rejections should be withdrawn.

**IV. The Examiner’s Proposed Language Would Logically Exclude the Admittedly Enabled Features of the Claimed Invention.**

On the other hand, the Examiner’s proposed closed transitional phrase “consists of,” would so drastically narrow the claims so as to be entirely prohibitive of the additions which the dependent claims proffer on the invention, additions which are all described and fully supported in the specification. “The transitional phrase ‘consists of’ excludes any element, step, or ingredient not specified in the claim.” MPEP 2111.03, quoting *In re Gray*, 53 F.2d 520 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). “A claim which depends from a claim which ‘consists of’ the recited elements or steps cannot add an element or step.” *Id.* Here, the Examiner would have Applicant place the limiting “consists of” immediately following the preamble of the claim and, in the process, preclude every one of its dependent claims, which the Examiner herself has stated are enabled and would be allowable if presented in independent form. For example, claims 2 and 3 place a specific amino acid at the respective amino and carboxy termini. Claim 7 limits the peptide to a nonapeptide. Claim 8 and 34 requires that the sequence possess SEQ ID NO 2, which contains selected variable amino acids. Claims 9 and 34 limit those variations to derivatized amino acids and claims 10, 35 and 36 even further to specific amino acids. Claim 12 is limited to a peptide with SEQ ID NO 5. All of these variations to the sequence make clear that variations of the peptide sequence are properly enabled. This is, in fact, the reason why the transitional phrase “consists essentially of” is used – e.g., to avoid every claim having to be independent.

Because the features of the dependent claims are fully enabled and described, according to the Examiner and her Supervisor’s own admissions, for at least these reasons, so must at least the transitional phrase “consists essentially of.”

**V. Applicant Arguments Made Against All 35 U.S.C. § 112, Second Paragraph, are Presumed Withdrawn In Light of Arguments Made in the AF Response.**

The Advisory Action does not repeat or otherwise comment on the rejections of claims 1-19 and 25-41 based on 35 U.S.C. § 112, second paragraph, for alleged indefiniteness because of the terms “effective” in claim 1 and the

phrase “low toxicity and a low incidence” in claim 28. Applicant therefore assumes that the arguments made in the Response to the final Office Action were found persuasive on this issue and will not reiterate at length those legal and factual arguments here except to emphasize again that these are terms of art which are neither relative nor undefined to a person skilled in the art. Additionally, the terms are defined and supported in the last full paragraph of page 10 of the specification (for “effective”) and on pages 9 and 26-27 of the specification (for “low toxicity” and “low incidence”). Applicant respectfully request that the rejection based on alleged indefiniteness be explicitly withdrawn. But in addition, should the enablement rejections be withdrawn, Applicant would be willing to amend these phrases or otherwise delete these claims to obtain an allowance.

**VI. The Examiner Ignores Applicant’s Arguments from the AF Response**

The Advisory Action, although lengthy, does not repeat the Examiner’s and the Supervisory Examiner’s allegations that literal support must be found in the specification for the term “consists essentially of,” but imposes all new arguments. Therefore, Applicant assumes that the legal arguments made in the AF Response were found persuasive on this issue and will not reiterate them here. However, in having conceded that the only possible argument against the phrase “consists essentially of” (that no literal support existed for the phrase) could not stand up to legal scrutiny, the Examiner and her Supervisor have simply reverted to repeating the same erroneous, moot or irrelevant statements made in the non-final Office Action. Applicant considers its arguments to be un-refuted and, therefore, the enablement rejections should be considered moot.

**VII. Conclusion**

For at least these reasons, Applicant respectfully requests that all 35 U.S.C. § 112 rejections be withdrawn and the prompt issuance of a Notice of Allowance. In the alternative, should the rejections not be withdrawn, Applicant respectfully requests that the application be fully and properly examined, and also that Applicant’s amendment be entered for the purpose of proceeding with the Appeal.

In the event that any additional fees are deemed necessary with the filing of this Request, the Commissioner is authorized to charge those fees to the undersigned’s Deposit Account No. 14-1437 referencing Attorney Docket No. 8109.005.US.

Date: July 20, 2007

Respectfully submitted,  
Novak Druce & Quigg LLP  
By: \_\_\_\_\_

James Remenick  
Registration No. 36,902

**Customer No. 69911**  
Novak Druce & Quigg LLP  
1000 West Tower  
1300 Eye Street, NW; Washington, DC 20005  
(202) 659-0100 (telephone); (202) 659-0105 (facsimile)